



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-4711]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Nonbinding Feedback After Certain FDA Inspections of Device Establishments.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requests for Nonbinding Feedback After Certain FDA Inspections of Device Establishments

OMB Control Number 0910-NEW

The guidance document entitled “Nonbinding Feedback After Certain FDA Inspections of Device Establishments” explains how the owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA Inspectional Observations Form (Form FDA 483) and issued to the firm upon completion of an inspection of the firm’s establishment. The guidance also identifies a standardized method for communicating and submitting requests for nonbinding feedback and describes how FDA evaluates and responds to such requests.

In the *Federal Register* of February 19, 2019 (84 FR 4823), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received comments on the following PRA related topics:

FDA received several comments regarding whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility.

(Comment 1) One commenter requested that FDA clarify the benefits of requesting nonbinding feedback (e.g., whether nonbinding feedback, and a subsequent reaction to that feedback) could prevent a Warning Letter from being issued.

(Response) FDA believes that the benefits of requesting nonbinding feedback are clear. Specifically, timely nonbinding feedback could help firms determine whether proposed actions to address inspectional observations are adequate, possibly avoiding unnecessary investment in potential solutions not likely to satisfactorily address an inspectional observation. FDA's considerations and procedures for determining whether a Warning Letter should be issued are identified in other documents (e.g., FDA's Regulatory Procedures Manual).

(Comment 2) Multiple commenters felt that the guidance applies narrow criteria that forecloses meaningful access to Agency feedback. For example, some commenters felt that FDA should provide feedback on any emerging safety issue, not just those that are likely to cause death or serious injury.

(Response) Section 704(h)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374(h)(2)) sets forth eligibility criteria for a request for nonbinding feedback. FDA's guidance describes situations involving significant observations that the Agency believes meet the statutory criteria. In addition, we note that firms have other options to engage with FDA.

FDA received several comments related to ways to enhance the quality, utility, and clarity of the information to be collected.

(Comment 3) Multiple commenters asked whether findings from Medical Device Single Audit Program (MDSAP) audits are eligible to receive nonbinding feedback.

(Response) The Medical Device Single Audit Program is a voluntary program that allows an MDSAP-recognized Auditing Organization to conduct a single regulatory audit of a medical

device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. MDSAP audits do not meet the definition of an inspection set forth in section 704 of the FD&C Act; therefore, findings from MDSAP audits are not eligible to receive nonbinding feedback.

(Comment 4) One commenter stated that the guidance contradicts least burdensome principles.

(Response) FDA disagrees with the comment. As stated in FDA's guidance, "The Least Burdensome Provisions: Concepts and Principles"¹, FDA defines "least burdensome" to be "the minimum amount of information necessary to adequately address a relevant regulatory question or issue through the most efficient manner at the right time." FDA believes that the nonbinding feedback program is fundamentally "least burdensome," because it strives to help firms avoid unnecessary investment in potential solutions not likely to satisfactorily address an inspectional observation. By providing a mechanism in which firms can, voluntarily, seek nonbinding feedback on proposed actions to address certain inspectional observations, the program seeks to help firms resolve regulatory issues through the most efficient manner at the right time, using the minimum amount of information necessary.

(Comment 5) One commenter asked whether outputs of the draft guidance, such as requests for nonbinding feedback or FDA's responses to requests for nonbinding feedback, will be placed in a public database.

(Response) The FD&C Act does not require requests for nonbinding feedback or FDA's responses to requests for nonbinding feedback to be placed in a public database. However, FDA

¹The guidance is available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>.

may take additional actions (e.g., issue Warning Letters or safety communications) in response to significant inspectional observations, some of which may be posted publicly.

(Comment 6) Multiple commenters requested that FDA extend the “deadline” for requesting nonbinding feedback beyond 15 days after issuance of a Form FDA 483. For example, some commenters felt that imposing a 15 day “deadline” for requesting nonbinding feedback would result in rushed remediations without a sufficient understanding of the root-cause of the underlying quality system deviations.

(Response) Firms are not required to submit requests for nonbinding feedback. To be eligible for nonbinding feedback, a request for nonbinding feedback must involve a public health priority, implicate systemic or major actions, or relate to emerging safety issues. FDA believes that a corrective action should be taken as expeditiously as possible in response to an observation that meets one or more of the statutory criteria. In situations where a firm is unable to submit a timely request for nonbinding feedback, the firm has other options to engage with FDA.

(Comment 7) Multiple commenters requested that FDA allow multiple chances to seek nonbinding feedback. For example, some commenters stated that a firm’s initial corrective action plan may change over time and that remediation may take months; therefore, firms may need feedback more than once and more than 15 days after issuance of a Form FDA 483.

(Response) FDA believes that inspectional observations that involve a public health priority, implicate systemic or major actions, or relate to emerging safety issues should be corrected as expeditiously as possible. FDA acknowledges that in some situations, firms may desire feedback more than once. If multiple requests for nonbinding feedback are timely and meet the other statutory requirements, FDA is required to respond to each request within 45

days. If multiple requests for nonbinding feedback are not timely, then these requests will not be subject to a response from FDA within 45 days.

Finally, FDA acknowledges that when the inspectional observations involve a public health priority, implicate a systemic or major action, or relate to an emerging safety issue, continued communication between FDA and the firm may be needed after issuance of the nonbinding feedback to ensure adequate protection of public health. In such cases, FDA may continue communication with the firm and/or take any action necessary to ensure adequate protection of public health.

FDA received one comment regarding ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

(Comment 8) One commenter requested that FDA develop templates for manufacturers to submit when requesting nonbinding feedback.

(Response) At this time, FDA does not believe that providing a template would be appropriate since the content of the request for nonbinding feedback is expected to be situationally dependent and different firms may have different preferred formats for requesting nonbinding feedback. FDA believes that use of a template may be too restrictive and could result in pertinent information not being included in the request for nonbinding feedback. Nonetheless, FDA may choose to utilize a template at a later date if it determines it would be beneficial to firms to do so.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for nonbinding feedback after certain FDA inspections of device establishments	220	1	220	500	110,000

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate that 220 respondents per year will request nonbinding feedback is based on recent inspectional data. Based on the recommendations in the guidance and our experience with similar information collections, we believe it will take approximately 500 hours to complete a request for nonbinding feedback. Therefore, we estimate the burden of this information collection to be 110,000 hours.

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-05131 Filed: 3/12/2020 8:45 am; Publication Date: 3/13/2020]